

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Kirk Hogan
Serial No.: 09/976,423 Group No.: 1634
Filed: 10/21/2001 Examiner: J.A.. Goldberg
Entitled: **Methods and Compositions for Perioperative Genomic Profiling**

**DECLARATION OF KIRK HOGAN, M.D.,
UNDER 37 C.F.R. §1.132**

EFS Web Filed

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Examiner,

I, Kirk Hogan M.D., do hereby declare as follows:

1. I, Kirk Hogan, am the inventor of the subject matter embodied in the above-identified patent application.
2. I am a licensed and board-certified anesthesiologist, and am a Professor in the Department of Anesthesiology at the University of Wisconsin School of Medicine and Public Health in Madison, Wisconsin.
3. As an instructor and licensed and board-certified practitioner, I am knowledgeable about the practice of anesthesiology.
4. I have been a teacher of anesthesiology for over 20 years, and have participated in the training of over 100 anesthesiologists.
5. For many decades before the perioperative genomic profile kits of the present patent application, anesthesiologists were highly motivated to detect multiple risks for complications before, during and after a surgical procedure associated with genetic variations. Nevertheless, anesthesiologists did not arrive at the kits of the presently claimed invention. Thus, the perioperative genomic profile kits of the present patent application clearly fulfill a long felt, but hitherto unmet need.
6. Prior to the perioperative genomic profile kits of the present patent application, the anesthesiologist of ordinary skill was not aware of kits for genomic analysis of single polymorphisms, single genes or single diseases.

7. Prior to the perioperative genomic profile kits of the present patent application, the anesthesiologist of ordinary skill did not use kits for genomic analysis of single polymorphisms, single genes or single diseases.

8. Prior to the perioperative genomic profile kits of the present patent application, the anesthesiologist of ordinary skill was not aware of kits for genomic analysis of multiple polymorphisms, multiple genes or multiple diseases.

9. Prior to the perioperative genomic profile kits of the present patent application, the anesthesiologist of ordinary skill did not use kits for genomic analysis of multiple polymorphisms, multiple genes or multiple diseases.

11. While the anesthesiologist of ordinary skill has for many decades recognized that inborn predispositions are significant contributors to morbidity and mortality in the interval surrounding surgery, anesthesiologists of ordinary skill could not have combined the claimed elements because they lacked the requisite appreciation of the technical knowledge to arrive at the perioperative genomic profile kits of the presently claimed invention as a solution to the problems addressed by the presently claimed invention.

The undersigned declares further that all statements made herein of his own knowledge are true, and all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are so made punishable by fine or imprisonment, or both, under §101 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dated: December 17, 2007 Signed: K. Hogan